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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,123	02/18/2004	Mark W. Kroll	A04P1016US01	5391

36802 7590 09/12/2006

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
BERTRAM, ERIC D	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,123	KROLL, MARK W.	
	Examiner	Art Unit	
	Eric D. Bertram	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/18/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 2/18/2004 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: in paragraph 0001 of the specification, the blank Application number should be filled in with "10/782,684".

Appropriate correction is required.

Claim Objections

3. Applicant is advised that should claim 2 be found allowable, claim 21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/782,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both describe methods and apparatuses for recording diagnostic data in an implantable device based on the detection of predetermined triggers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 9, 10, 12-14, and 21-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al. (US 5,908,392, hereinafter Wilson). Wilson discloses a

system and method for recording and storing medical data in response to a programmable trigger. Wilson describes that triggers may be modified and set by a medical practitioner in order to ensure that only necessary data is stored, as deemed by the practitioner (Col. 12, lines 50-61 and Col. 4, lines 10-15). Since the triggers are set by the practitioner, they are inherently chosen by evaluating the likelihood of important diagnostic data being associated with the predetermined triggers. Based on these predetermined triggers, the system will record data prior to, during and subsequent to important cardiac episodes that are being monitored by the system (Col. 4, lines 4-8). Wilson states that the data to be recorded can include IEGMs and event records (Col. 7, lines 40-65). Furthermore, the triggers can include fast beat threshold values between 90 and 200 bpm (Col. 9, lines 21-25) as well as and morphology thresholds, which in this case are consecutive premature ventricular contractions (PVC) or pacemaker-mediated tachycardia (PMT) (Col. 9, lines 30-45). Finally, Wilson discloses that the data is held in a temporary snapshot buffer prior to being moved and stored in permanent memory (Col. 9, line 54-Col. 10, line 22).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 7, 8 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson. Wilson, as described above, discloses the applicant's basic invention with the exception of specifically disclosing the medical practitioner reviews the data in order to determine if the triggers were correctly set to record important diagnostic data. However, Wilson does disclose that the practitioner reviews the data recorded during follow-up visits in order to appraise the performance of the implantable device (Col. 4, lines 28-41). While it is not stated, one of ordinary skill would assume that if the data recorded was not found to be adequate, then the practitioner would adjust the recording triggers accordingly in order to capture the best data possible in the future. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the method of Wilson by varying the triggers after appraisal of the implantable device in order to record the best and most prevalent data possible in order to provide the best care possible to the patient.

11. Regarding claims 16 and 17, Wilson discloses counting the number of consecutive beats that have PVC or PMT and when the occurrence is 1-15 consecutive times initiating recording of the data (Col. 9, lines 30-45).

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson in view of Official Notice. Wilson, as described above, discloses the applicant's basic invention with the exception of using heart rate variability changes as an indication of arrhythmia. However, the Examiner takes Official Notice that changes in heart rate variability is notoriously well known to those skilled in the art as a strong indicator of cardiac arrhythmia, specifically T-wave alternans. Therefore, it would have been obvious to one of ordinary skill in the art to modify the method of Wilson to incorporate heart rate variability (HRV) as a trigger since it is well known in the art that HRV is an indicator of cardiac arrhythmia.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: van Lake et al. (US5,785,660) discloses a method for storing IEGMs in an imp0lantable device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766

Robert E. Pezzuto
Supervisory Patent Examiner
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EDB